Inquiring Minds

News and notes from the Department of Clinical Investigation
Walter Reed Army Medical Center
Washington, D.C.

October 2002

DCI, Research Operations Service, is Relocating to Bldg 7!

The Department of Clinical Investigation, Research Operations Service (ROS) will soon be relocating from Bldg T-2 to Bldg 7.

The DCI research laboratory is currently housed in the temporary building of T-2. With the structural renovation of Bldg 7 expected to be completed late October, DCI's research laboratory will then expand to the ground, second, and third floors of that building with modern, state-of-the-art laboratories and offices.

According to Mr. Maged Abdel-Rahim (Chief, ROS): "The different functions of the ROS operation will be spreading over the ground and the second floor. The attic (third flood) will be used for storage of lab supplies, excess small equipment, etc. There is a designated area for metal analysis and mass spectroscopy on the ground floor which is environmentally controlled. There is an area designated for cell culture only on the ground floor. Also we have a separate area for radioisotopes work."

"The 3 sections (chemistry, immunology/molecular biology and experimental pathology) will be located on the rest of the remaining area according to the work of these functions. We will have 19 offices, a break area and a conference room on the second floor."

DCI, ROS Moving to Bldg 7

As for the moving date from building T-2 to building 7, this date has still not been determined.

While the location of ROS will be changing, the mission will remain the same: to support basic and clinical laboratory research by providing services and training in chemistry, immunology, and molecular biology for DCI-approved protocols. ROS will continue to have accessible laboratory space, state-of-the-art equipment and highly trained personnel to support and consult on research techniques, equipment, and method development.

The support and equipment provided by the various sections of ROS are listed on the DCI website.

New Continuing Education Research Course Requirement for WRAMC PIs

Federal regulations require education and training on the protection of human research subjects for all investigators. As a result, the Department of Clinical Investigation (DCI) currently has two training options available to WRAMC investigators: the Collaborative IRB Training Initative (CITI) Web-based Research Course and the onsite "live" Research Course. Completion of ONE of these courses is required for all individuals wishing to serve as a Principal Investigator (PI) on a WRAMC research protocol and is highly encouraged for all personnel involved in research.

These two options serve to provide a fundamental knowledge for new researchers. However over the last 3-4 years, Federal regulatory agencies have strongly encouraged and advocated for the creation of continuing education programs on research.

As of **1 November 2002**, after having obtained approval from the WRAMC Professional Education and Training Committee, the WRAMC research program will also require completion of the CITI Continuing Education Course for all PIs that have not completed one of the two basic training requirements listed above in the past

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Inside This Issue

Increasing Lawsuits Against Medical Researchers & IRBs

As highlighted in a recent *Boston Globe* article[1], lawsuits are increasingly targeting medical researchers. While malpractice suits against physicians are known, medical researchers conducting clinical trials were rarely if ever sued. That trend has seemed to change in the past decade.

Several high-profile suits, including that filed by the family of Jesse Gelsinger who died in 1999 in a gene therapy trial at the University of Pennsylvania, has focused national attention on the protection of study participants. While the percentage of lawsuits against medical researchers remains small, many experts believe this percentage will only increase due to the surge in clinical trials in recent years.

Many of these lawsuits are focusing on alleged ethical violations such as inadequate oversight or hidden financial conflicts. An increasing trend is to include the Institutional Review Board (IRB) as a defendant, alleging inadequate protection of human subjects. While the courts have yet to hold an IRB liable, some institutions claim the suits are making it more difficult to recruit IRB members.

One of the first and most well known cases involving suing the IRB involved participants in a cancer clinical trial at the University of Oklahoma Health Sciences Center in Tulsa[2]. That trial was suspended after an audit found inadequate protections for human subjects and a lawsuit was later filed alleging that their constitutional right to be treated with dignity had been violated. The complaint named all members of the IRB as defendants.

The Office for Human Research Protections (OHRP) found that "the IRB failed to conduct substantive and meaningful continuing review," said a June 29, 2000, letter suspending all federally funded research at the university. Further, the informed consent documents approved by the Tulsa IRB failed to describe the risks of the trial and overstated its foreseeable benefits. "[S]ubjects were unlikely to benefit ... given that this was a phase I study of a vaccine never before administered to human subjects," OHRP concluded.

Another case concerning suing members of an IRB involve the University of California at Los Angeles. In this lawsuit, the patient and his parents allege that the university misled them about the risks of a study on withdrawing medication from people with schizophrenia. The case has been joined with another filed by the parents of an additional participant in the trial, who committed suicide in 1991.

An additional case involves a Philadelphia woman who alleges she lost complete control of her bowels due to a clinical trial she participated in at the Graduate Hospital of Philadelphia. Her lawsuit includes the IRB that approved the clinical trial.

What does this increase in lawsuits mean for the future of clinical research? What does this mean for IRB members and in particular Department of Defense IRB members? Are WRAMC IRB members now at an increased risk of being sued?

The questions were posed to Mr. Scott Murdoch, HUC representative from the Center Judge Advocate Office. Mr. Murdoch stated, “The present possibility for damaging clinical research in the greater community seems rather small, and smaller still within the Department of Defense. As far as we (the WRAMC HUC and researchers) are concerned, there is no prospect of being sued *individually* for negligence related to medical research for the same reasons there is no prospect for being sued for medical malpractice.”

“Federal employees, including military personnel, are not generally personally liable for alleged injuries arising out of the execution of official duties. Medical personnel are protected by a specific statute, which transfers liability exclusively to the United States. Medical personnel engaged in authorized research and members of the HUC and CIC who approve the research are presumably acting within the scope of their official duties and would not be individually liable. However, this does not mean that a claim could not be filed against the United States for injuries allegedly arising from research.”

While WRAMC IRB members may not be personally liable while carrying out their official duties, COL James Lamiell (Chief, Clinical Investigation Regulatory Office) stated, “IRBs and investigators are certainly liable to do the right thing. The message to investigators and IRBs is: do your job well.”

[1]Dembner, A. **Lawsuits Target Medical Research.** *Boston Globe*, 12 Aug 2002; A1.

[2]Foubister, V. **Clinical Trial Patients Sue IRB Members.** *American Medical News*, 26 Feb 2001; 44(8).

“Investigator 101” CD-ROM Now Available

The **Investigator 101 CD-ROM** was produced by the Public Responsibility in Medicine and Research (PRIM&R) organization and provides education on the responsible conduct of human research and protection of human subjects. The course contains two presentations, Part 1: “The History and Ethics of Human Subject Research”, with Dr. Jeffrey Cooper (Chair, IRB Albany Medical Center), and Part 2: “The Top 10 Responsibilities of Investigators”, with Ms. Ada Sue Selwitz (Office of Research Integrity, University of Kentucky). Both talks are divided into short modules. Written transcripts of the talks and a comprehensive set of hyper-linked references and reading materials are also available. For more information on the CD-Rom see: www.primr.org/101cdrom.html.

Copies of the CD-ROM are available to WRAMC researchers at no charge. For your free copy, please call DCI at 202-782-6389.

Statistical Analysis Using SPSS: Levels 1, 2, & 3

The DCI, Research Review Service, will be offering a three-part series of workshops to help the clinical investigator learn SPSS statistical analysis software & concepts.

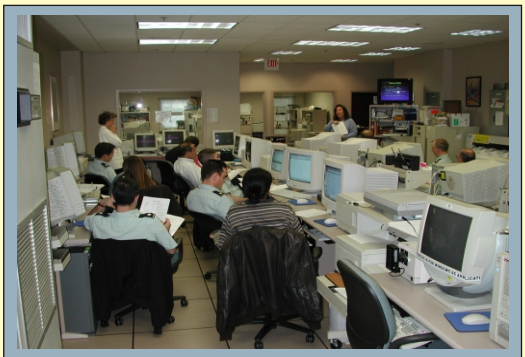
These courses are for military and civilian clinician researchers (and aspiring researchers) at WRAMC and designed to give 'hands-on' experience in utilizing statistical analysis software. The content of each session is as follows:

Level I: An Overview of Data Coding and Data File Creation
Level II: Statistical Methods for Comparing Differences between Two Groups
Level III: Nonparametric Statistics in Health Care Research

The course will be limited to 12 participants and is free of charge to WRAMC personnel. Each participant will attend all three courses with Level I a prerequisite for Levels II and III.

The course will meet on 3 consecutive Thursday afternoons in November (7, 14, 21 November) from 1330-1530. The courses are held in the DCI Computer Room (Bldg 6, Room 4075).

For further information and future course dates, see www.wramc.amedd.army.mil/departments/dci/statclass.htm.



Scene from a recent SPSS course

Registration Deadline for Next Research Course is 4 October!

The next WRAMC Research Course, presented by the Department of Clinical Investigation, is scheduled for Thursday, 17 October 2002. This one-day course will be held from approximately 0800 to 1600 in Sanford Auditorium at the Uniformed Services University of the Health Sciences (USUHS) in Bethesda, MD. Deadline for registration is **4 October**.

The course is open to physicians, nurses, dentists, and other health care personnel who will conduct clinical, animal or laboratory research at WRAMC. The course consists of a full day of training, targeted to new investigators and to those who have not completed a Research Training Course and desire to start a research protocol. Completion of this course is required for all individuals wishing to serve as a Principal Investigator (PI) on a WRAMC research protocol and for Research Coordinators. The course is also highly encouraged for all personnel involved in research to include associate investigators, data analysts, etc.

The objective of this course is to educate WRAMC medical personnel on the ethical issues, current regulations, and design considerations in conducting medical research.

Topics for this course include: an overview of DCI and resources available to investigators; elements on obtaining informed consent; commonly-made mistakes in protocol applications and how to avoid them; scientific misconduct; tissue banking; and publication issues. Certificates will be given at the completion of the sessions.

Registration is available on the DCI web page or by calling Mr. Dan Rosen at (202) 782-6389. The deadline for registration is **4 October**. There is no registration fee for active duty military or Walter Reed civilian investigators.

CITI Web Based Research Course Reminder

DCI would like to remind all current and potential Principle Investigators, Associate Investigators, and Research Coordinators that a new web based research course is now available. DCI has elected to use the Collaborative IRB Training Initiative (CITI) Human Subjects Research Education Module, which is operated and maintained by the University of Miami. For more information and to register for this course, see the DCI website.

Fludarabine-Related Pulmonary Toxicity: A Distinct Clinical Entity in Chronic Lymphoproliferative Syndromes*

In this section of the newsletter, DCI randomly picks a WRAMC department/service and profiles a recent article of interest by that department/service. This article profiles a joint venture by Department of Medicine, Allergy & Immunology Service, Hematology & Oncology Service and Pulmonary & Critical Care Medicine Service.

Fludarabine, which is more and more commonly being used in a variety of malignant conditions, has multiple side effects and has been associated with pulmonary toxicity. Despite the wide use of fludarabine therapy, little clinical data is available regarding this agent and pulmonary toxicity.

In an effort to establish a case definition, to describe management, and to identify risk factors for fludarabine-related pulmonary toxicity, Walter Reed Army Medical Center researchers identified individuals who were treated with fludarabine at WRAMC between January 1989 and June 2000.

One of the researchers, CPT Donald Helman, stated: "Prior to our project there had been several isolated case reports of pulmonary toxicity related to fludarabine therapy. We had seen cases at WRAMC but did not really have any formal framework with which to approach these patients."

Cases of fludarabine-related pulmonary toxicity were defined as follows: dyspnea, fever, hypoxemia, and radiographic infiltrates seen in patients treated with fludarabine. Cases were excluded if there was evidence of pulmonary infection or progression of underlying lymphoproliferative disease affecting the lungs. For each case, demographic data, medical history, radiographic information, available bronchoscopy and pathology data, and details of treatment were reviewed.

Cases were compared with fludarabine-treated control subjects to identify potential risk factors. Comparisons were made with regard to age, gender, history of underlying lung disease, lymphoproliferative diagnosis, prior chemotherapy, fludarabine treatment regimen, and pretreatment chest radiograph.

The results were that during the study period, 105 patients were treated with fludarabine. The incidence of fludarabine-related pulmonary toxicity was 8.6% (9 patients). One patient died before this entity was suspected; the remaining eight patients underwent bronchoscopy to exclude infection and were treated with corticosteroids. One patient later died of apparent infection during steroid therapy. One patient was retreated with fludarabine and symptoms of lung toxicity developed again.

Comparisons were made between the group of patients with and without fludarabine-related pulmonary toxicity. Patients (n = 9) were similar to control subjects (n = 96) with respect to age, gender, history of underlying lung disease, previous chemotherapy, and fludarabine regimen.

The researchers did find that patients given fludarabine for chronic lymphocytic leukemia (CLL) are more likely (over 13 times more) to develop pulmonary toxicity. It is uncertain whether this is related to the immunobiology of CLL or to the other factors associated with differences in patients with CLL compared to the other lymphoproliferative disorders. There was a trend toward a significant difference between those patients who had pre-treatment chest x-rays demonstrating interstitial infiltrates.

While fludarabine is generally safe and well tolerated, these researchers concluded that this agent causes direct pulmonary toxicity. After performing an appropriate evaluation to exclude infection, corticosteroids are an effective therapy. The relative frequency of this condition and potential for mortality underscore the need for increased clinician awareness of fludarabine-related pulmonary toxicity and its risk factors.

CPT Helman noted: "What, I hope, we accomplished with this article was 1) created a more formal definition of fludarabine related pulmonary toxicity, hopefully this should allow for further research in this area and 2) gained an appreciation for just how common this entity might be."

*Helman DL Jr, Byrd JC, Ales NC, Shorr AF. **Fludarabine-related pulmonary toxicity: a distinct clinical entity in chronic lymphoproliferative syndromes.** *Chest* 2002 Sep;122(3):785-90.

DCI is SHARPP..

Striving to
Help
All
Researchers from
Planning to
Publication

Recent WRAMC publications

Congratulations to the following WRAMC investigators on their recently published papers. This list was compiled from a recent MEDLINE search of the literature. Listed articles have been cleared through DCI and the WRAMC Public Affairs Office. If you have recently published, and we have not included your publication, please let us know so we may list your publication in the next issue of the newsletter.

Lawson S, Ward DT, Conner C, Gallagher C, Tsokos G, Shea-Donohue T. **Diabetic hyperglycemia: a facilitating factor in systemic capillary leak.** *J Surg Res.* 2002 Jun 15;105(2):95-101.

Surr RK, Walden BE, Cord MT, Olson L. **Influence of environmental factors on hearing aid microphone preference.** *J Am Acad Audiol*. 2002 Jun;13(6):308-22.

Cord MT, Surr RK, Walden BE, Olson L. **Performance of directional microphone hearing aids in everyday life.** *J Am Acad Audiol.* 2002 Jun;13(6):295-307.

Abbott KC, Hypolite IO, Agodoa LY. **Sickle cell nephropathy at end-stage renal disease in the United States: patient characteristics and survival.** *Clin Nephrol*. 2002 Jul;58(1):9-15.

Belmont PJ Jr, Klemme WR, Robinson M, Polly DW Jr. **Accuracy of thoracic pedicle screws in patients with and without coronal plane spinal deformities.** *Spine.* 2002 Jul 15;27(14):1558-66.

Argyros G, Cassimatis DC, Argyros G. **A 55-year-old mechanically ventilated male requiring aeromedical evacuation.** *Mil Med.* 2002 Jul;167(7):606-9.

Liu X, Engel CC Jr, Cowan D, McCarroll JE. **Using general population data to project idiopathic physical symptoms in the U.S. Army.** *Mil Med.* 2002 Jul;167(7):576-80.

Shorr AF, Davies DB, Nathan SD. **Outcomes for patients with sarcoidosis awaiting lung transplantation.** *Chest.* 2002 Jul;122(1):233-8.

Abbott KC, Musio FM, Chung EM, Lomis NN, Lane JD, Yuan CM. **Transjugular renal biopsy in high-risk patients: an American case series.** *BMC Nephrol.* 2002 Jul 11;3(1):5.

Batty DS Jr, Swanson SJ, Kirk AD, Ko CW, Agodoa LY, Abbott KC. **Hepatitis C virus seropositivity at the time of renal transplantation in the United States: associated factors and patient survival.** *Am J Transplant.* 2001 Jul;1(2):179-84.

Henderson CG, Griewe GL, Siegel TS, Peppas DS, Esther TA, Moul JW. **Rapidly progressing adenocarcinoma of the prostate presenting as prostatitis.** *J Urol.* 2002 Aug;168(2):638-9.

Wortmann G, Miller RS, Oster C, Jackson J, Aronson N. **A randomized, double-blind study of the efficacy of a 10- or 20-day course of sodium stibogluconate for treatment of cutaneous leishmaniasis in United States military personnel.** *Clin Infect Dis.* 2002 Aug;35(3):261-7.

Katial RK, Grier TJ, Hazelhurst DM, Hershey J, Engler RJ. **Deleterious effects of electron beam radiation on allergen extracts.** *J Allergy Clin Immunol.* 2002 Aug;110(2 Pt 1):215-9.

Abbott K, Hypolite I, Viola R, Poropatich R, Hshieh P, Cruess D, Hawkes C, Agodoa L. **Hospitalizations for cytomegalovirus disease after renal transplantation in the United States.** *Ann Epidemiol.* 2002 Aug;12(6):402.

Betts AM, Mitchell GL, Zadnik K. **Visual performance and comfort with the Rose K lens for keratoconus.** *Optom Vis Sci.* 2002 Aug;79(8):493-501.

Engel CC Jr. **Caring for medically unexplained physical symptoms after toxic environmental exposures: effects of contested causation.** *Environ Health Perspect.* 2002 Aug;110 Suppl 4:641-7.

Ellis MW, Oster CN, Turiansky GW, Blanchard JR. **A case report and a proposed algorithm for the transfer of patients with Stevens-Johnson syndrome and toxic epidermal necrolysis to a burn center.** *Mil Med.* 2002 Aug;167(8):701-4.

Parker MF, Mooradian GC, Okimoto GS, O'Connor DM, Miyazawa K, Saggese SJ. **Initial neural net construction for the detection of cervical intraepithelial neoplasia by fluorescence imaging**. *Am J Obstet Gynecol.* 2002 Aug;187(2):398-402.

Moul JW, Wu H, Sun L, McLeod DG, Amling C, Lance R, Kusuda L, Donahue T, Foley J, Chung A, Sexton W, Soderdahl D, Rich NM. **Epidemiology of radical prostatectomy for localized prostate cancer in the era of prostate-specific antigen: An overview of the Department of Defense Center for Prostate Disease Research national database.** *Surgery* 2002 Aug;132(2):213-219.

Miner TJ, Jaques DP, Shriver CD. **A prospective evaluation of patients undergoing surgery for the palliation of an advanced malignancy.** *Ann Surg Oncol. 2002 Aug-Sep;9(7):696-703.*

Engler RJ, Kenner J, Leung DY. **Smallpox vaccination: Risk considerations for patients with atopic dermatitis.** *J Allergy Clin Immunol.* 2002 Sep;110(3):357-365.

Elgin E, O'Malley P, Feuerstein I, Taylor A. **Frequency and severity of "incidentalomas" encountered during electron beam computed tomography for coronary calcium in middle-aged Army personnel.** *Am J Cardiol.* 2002 Sep 1;90(5):543.

Abbott KC, Agodoa LY. **Hospitalizations for valvular heart disease in chronic dialysis patients in the United States.** *Nephron.* 2002 Sep;92(1):43-50.

Caravalho J, O'Donnell SD, Feuerstein IM, O'Malley PG, Gillespie DL, Goff JM, Sherner J, Petten M, Taylor AJ. **Preoperative Risk Stratification Using Electron Beam Computed Tomography in Elective Vascular Surgery: Relationship to Clinical Risk Prediction and Postoperative Complications.** *Ann Vasc Surg* 2002 Sep12.

Helman DL Jr, Byrd JC, Ales NC, Shorr AF. **Fludarabine-related pulmonary toxicity: a distinct clinical entity in chronic lymphoproliferative syndromes.** *Chest 2002 Sep;122(3):785-90.*

FAQs Regarding Submitting an Annual Progress Report (APR)

This article hopes to clarify any questions/concerns that a principal investigator (PI) may have in reference to the Annual Progress Report (APR).

Why do I have to submit an APR?
The APR is part of the continuing review process mandated by federal regulations to assure that the protection of human research subjects are appropriate, and to determine if progress to date warrants continuation of the study. All research is required to be reviewed and re-approved at least once annually by the Institutional Review Board.

Will I be notified that I must submit an APR?
Once a year, two months prior to the protocol's anniversary month of approval date, DCI will initiate a request for an APR via Outlook with the necessary forms and instructions. These forms and information can also be obtained from the DCI web site under filename "APR-human.doc" (human study) or "APR-animal.doc" (animal study).

What does the APR consist of?
The APR consist of 3 enclosures:

1) A Detail Summary Sheet (to include adverse events, enrollment, etc)
2) Continuing Review of Research
3) List of Publications

For enclosure 1, check the "Ongoing" status, if the study is in one of the following conditions: subject accrual, follow-up, data collection, or data analysis. If the study has completed the data analysis and is in the process of reporting /presentation, you may check the "Complete" status. In the "Prior and Current Progress" section, be sure to include the number of subjects enrolled for the year and the total enrollment to date, also indicate any adverse events. State no adverse event when there is none. Make a copy of enclosure 2 and sign your (i.e., PI) name on the signature block. Fill the publication page (i.e., enclosure 3) according to the suggested format. If your study uses a consent form and enrollment in the study is ongoing, a legible copy of the most up-to-date DCI-stamped consent form needs to be submitted to DCI.

How do I submit my APR and what is the review & approval process?
The completed APR is then returned by e-mail or fax (202-782-3881) to the Research Review Service, DCI APR Coordinator by the submission deadline. The APR is first reviewed by a Primary reviewer from the HUC and then forwarded to the HUC for review and approval. Upon HUC approval, the PI will receive the APR with the WRAMC IRB approval stamp. This stamped APR should be filed in the Protocol Administrative Binder.

What happens if I fail to submit my APR?
Failure to submit an APR to the HUC for review and re-approval before the anniversary date will result in an immediate abeyance (i.e., suspension) of the study The abeyance means that you may not enroll any new subjects. In addition, you may not continue any research in presently involved volunteers, unless the withdrawal of medication or intervention could be deleterious to the subjects. No funding will be approved, and data collected cannot be used for publication. Abeyance status may be lifted by the HUC upon the receipt and approval of the APR. A protocol with an abeyance status for more than 60 days will be administratively terminated by the HUC. Data from studies that have been terminated may not be published or presented. At this time DCI will also notify the WRAMC Commander, the Office of Human Research Protection (OHRP), and any Sponsor if applicable.

Who is the POC at DCI for APRs?
Kristin Beltz at (202) 782-7848 or via Outlook.

Research Alert List Reminder!

In order to provide better service to Walter Reed researchers, DCI has established a Researcher Alert List.

The Researcher Alert List consist of important periodic updates on policy changes, procedures, regulations, etc. that directly impact Walter Reed medical researchers.

For example, DCI has been receiving a record number of new protocols in the past two months, and has made a number of changes to assure these protocols are reviewed in a timely manner. We will be announcing these changes on the Researcher Alert List shortly.

If you are a Principal Investigator, Associate Investigator, research nurse, or want to be kept informed of key research developments, it is important that you be included on this list.

In order to receive the Research Alerts, e-mail Ms. Marty Green at (202) 782-7864 or Marty.Green@na.amedd.army.mil, and request to be added to the Research Alert list.

New CE requirement for WRAMC PIs (from page 1)

three years. Recertification is also highly encouraged for all personnel involved in research.

Please note that new protocols received by DCI after this date with PIs that have not complied with this requirement may have their approval date delayed until this requirement is met. Previously trained investigators with ongoing protocols who have not been trained in the last three years need to complete this continuing education course to remain in good administrative standing.

This continuing education web course is case based and requires about 1-2 hours to complete. Each module has a quiz associated with it. The passing score is 70% and is based on the overall score from all the required modules.

For more information on the CITI continuing education course and to begin training see www.wramc.amedd.army.mil/Departments/dci/WebCourse-CE.htm.

Recently Approved Protocols at WRAMC

Congratulations to the following principal investigators on their recently approved protocols. The following protocols have been approved since the last issue.

Department of Medicine

Endocrinology Service

COL Robert A. Vigersky, MC	02-13009: An Assessment of Ocular Lens Fluorescence Measurements for the Detection of Diabetes: A joint Joslin Dibetes Center, Tripler Army Medical Center and Walter Reed Army Medical Center
COL Robert A. Vigersky, MC	02-13010EX: The Sensitivity and Specificity Of Stereoscopic Non-Mydriatic Digital Retinal Photography In Detecting Diabetic Retinopathy

Gastroenterology Service

CPT Marten Duncan, MC	02-14012: Use of a Hyperspectral Imaging System for Dysplasia Screenng in Patient's with Long Segment Barrett's Esophagus - A Pilot Study
CPT John J. Napierkowski, MC	02-14012E: Wireless Capsule Endoscopy (WCE): A Multicenter Retrospective Review

General Medicine

CPT Russel M. Peckham, MC	02-10011E: Evaluation of Interobserver Variability in the Radiographic Diagnosis of Idiopathic Pulmonary Fibrosis
CPT Mary Klote, MC	02-10012E: Practice Variations and Trends Among Government Physicians in the Prescribing of Allergy Immunotherapy

Hematology-Oncology Service

LTC Rickey C. Myhand, MC	02-16008: An Open-Label, Randomized Study to Develop a ScreeningTool for Functional Capacity in Anemic Subjects with Nonmyeloid Malignancies Receiving Chemotherapy and Darbepoetin alfa (NESP)
MAJ Jamie K. Waselenko, MC	02-16009: Randomized Study of Fludarabine and Cyclophosphamide With or Without Genasense (Bc1-2 Antisense Oligonucleotide) in Patients With Relapsed or Refractory Chronic Lymphocytic Leukemia (Protocol GL303)
COL Janine Babcock, MC	02-16010: Collection of Blood Components from Healthy Donors for In Vitro Research.

Infectious Disease

MAJ Edward Gorak, MC	02-16000E: Autologous Stem Cell Transplantation in Patients with Relapsed or Newly Diagnosed Metastatic Breast Cancer: The Effect of Prior Chemotherapy Regimens and Timing of Transplantation on Transplantation Outcome
CDR Sybil A. Tasker, MC	02-19004: In Vitro Immunogenicity Assessment of HIV Vaccine Candidates

Nephrology Service

LTC Kevin C. Abbott, MC	02-87001E: WRAMC's Web-based Electronic Health Portal

Pulmonary & Critical Care Medicine Service

MAJ David A. Kristo, MC	02-17010: Comparison of Efficacy and Safety of Zolpidem-MR 12.5 mg and Placebo in Patients with Primary Insomnia. A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study
MAJ Christopher W. Humphreys, MC	02-17017E: Inter-observer Variability in Scoring Systems for Pre-test Probability for Pulmonary Embolism
MAJ Christopher W. Humphreys, MC	02-17020E: Cost-Minimization Analysis of Two Algorithms For Diagnosing Acute Pulmonary Embolism

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Recently Approved Protocols at WRAMC (cont. from page 7)

Department of Nursing	
LTC Patricia A. Patrician, AN	02-75015: A Study of the Safety and Feasibility of Telenursing for Remote Cardiac Rehabilitation
LTC(R) Janice B. Agazio	02-75015E: Active Duty Women's health behaviors
Janice B. Agazio, DNSc, DAC	02-75016E: Referral Patterns for Recurrent Low Back Strain
CPT Stacy Usher, AN	02-75017E: Effects of Pregnancy on the Army Physical Fitness Test
Department of Obstetrics and Gynecology	
LTC Scott G. Rose, MC	02-43009: GOG #0185: A Phase III Randomized Study of Adjuvant Radiation Treatment Versus Radiation and Chemotherapy in Patients with Vulvar Cancer and Involved Nodes
LTC Scott G. Rose, MC	02-43011: GOG 0146M: A Phase II Evaluation of Tirapazamine (NSC #130181, IND, 45,525) in Combination with Cisplatin in the Treatment of Recurrent Platinum Sensitive Ovarian or Primary Peritoneal Cancer
MAJ Larry G. Maxwell, MC	02-44008: Early Detection of Gynecologic Cancer Using the Protomics Based SELDI-TOF Method and a Heuristic Aalgorithm of Data Analysis
Department of Pathology	
LTC Jo-Ann Andriko, MC	02-48004: Ultrasound-Mediated Tissue Preservation
MAJ Keith Kaplan, MC	02-48002E: Correlation of Reactive Cellular Changes on Cervicovaginal Cytology (Papanicolaou test) with Subsequent Cervical Biopsies and Pat Test Follow-up
Department of Pediatrics	
MAJ Andrew Bauer, MC	01-65001b: Preclinical Pilot Study to Determine if the Novel Tumor-Activated Fluoropyrimidine Carbamate Capecitabine (Xeloda, Hoffman-Laroche, Inc.) could be used to Treat Thyroid Carcinoma: Are cytidine deaminase, thymidine phosphorylase, dihydropyrimidine
LTC Kevin M. Creamer, MC	02-65007: Correlation of BIS Number and University of Michigan Sedation Scale in Sedated Pediatric Patients
COL Glenn E. Edwards, MC	02-66003: CCG A3961: Treatment for Infants and Children with Intermediated Risk Neuroblastoma, A phase III Intergroup CCG/POG Study
LTC Abigail Harmon, MC, USNR	2-65002E: Providers' Skills in Evaluating the Middle Ear
CAPT Joseph O. Lopreiato, MC, USN	02-65003E: Parent/Patient Satisfaction After Ambulatory Visits Performed By Pediatric Residents
LTC Kevin Creamer, MC	02-65000EX: Pediatric Residents Training, Experience, and Comfort with End of Life Issues
LTC Kevin Creamer, MC	02-65004E: Retrospective Review of WRAMC's Pediatric Sedation Unit Database
Department of Psychology	
Dr. Alvin Jones, Ph.D., DAC	02-73003EX: An Examination of the Validity of Three Sets of MMPI/MMPI-2 Personality Disorder Scales

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Clinical Research Meetings & Conferences

Below is a list of meetings and conferences focusing on various aspects of clinical research. For more information, please see the specific website:

10 October: Fostering Integrity in Research Environments. A one-day conference will be held at the National Academy of Sciences in Washington, DC, to discuss the recommendations that will be made in the Institute of Medicine (IOM) report on Fostering Integrity in Research Environments.
Ori.dhhs.gov/html/programs/upcomingconferences-workshops.asp

19 October: Certification Exam for IRB Professionals. ARENA is offering a certification examination for IRB professionals. Interested candidates should see the below website to obtain a candidate handbook and for the location of testing locations. The handbook lists topics covered and examples of relevant references, including pertinent regulations, one may review to prepare for the examination
www.primr.org/conferences.html

24-27 October: 5th Annul Meeting of the American Society for Bioethics and Humanities. This meeting will be held in Baltimore, MD and will serve as an arena for interdisciplinary exchange among professionals in the fields of bioethics and the medical humanities. Attendees gain valuable knowledge through a variety of formats including discussions, workshops, and paper and poster presentations.
www.asbh.org/meeting/

28-29 October: National Human Research Protections Advisory Committee (NHRPAC) meeting. NHRPAC meetings address a wide spectrum of issues regarding research involving human subjects. These meetings are scheduled to be held on a quarterly basis. Location of this meeting TBA. ohrp.osophs.dhhs.gov/nhrpac/mtgs.htm

28-29 October: Monitoring Clinical Trials For GCP Compliance-Advanced Level. This is a two-day training course in Washington, DC that provides comprehensive step-by-step methods for monitoring clinical trials for GCP compliance. This advanced level training course provides important aspects in understanding GCP requirements and clinical quality assurance overviews for ensuring FDA compliance. Review the complexities of the clinical compliance laws and the role of the FDA/CFR, OHRB/IRB for clinical research.
www.pharmatraining.org/monitorclintrialsadvanced/

7-9 November: Good Clinical Practices for Clinical Investigators Training Program. These courses intend to provide intensive training to Clinical Investigators and their study staff on Good Clinical Practices, FDA regulations and ICH Guidelines in order to provide them with the appropriate tools to conduct cleaner, safer, more efficient clinical trials. This course will be held in New Orleans, LA.
www.acrpnet.org/education/gcpla.html

16-18 November: Research Conference on Research Integrity. The 2002 ORI RCRI will gather scholars from different disciplines together to discuss crucial research problems, explore different research methods, and share research results, with the ultimate goal of furthering understanding about ways to foster integrity and deter misconduct in research. The conference will be held in Potomac, MD.
ori.dhhs.gov/html/programs/upcomingconferences-workshops.asp

17 November: The 17th Annual Meeting of the Applied Research Ethics National Association. This meeting will be held in San Diego, CA with topics for this meeting including: respect for communities when conducting research; defining minimal risk research; confidentiality risk; informed consent; research involving adolescents; adverse events; grant applications; and gene transfer research.
www.primr.org/arenaprogram2002.html

18-19 November: Protecting Human Subjects: What's Best? What Works? What's Worth Doing?, This meeting will be held in San Diego, CA with panel discussions including: Multinational Research; Protecting Research Subjects: informed consent; new technology; and evaluation of risk and benefit by an IRB.
www.primr.org/program2002.html

Research Course Requirement For Proxy PIs

All Principal Investigators (PIs) are required to take the WRAMC Research Course or the on-line CITI course, which can be accessed on the DCI website.

But sometimes the investigator serving in the PI capacity is not allowed (for administrative reasons) to be listed as the PI on the protocol application. The Department of Clinical Investigation informally refers to this person the "Proxy PI."

A Proxy PI may be a medical student, nursing student, NIH employee, University employee, or other individual who will be responsible for the day-to-day conduct of the study, but does not qualify to be the WRAMC PI.

Since the Proxy PI oversees the study on a daily basis, it is important that this person understand the ethical and regulatory issues of medical research. For this reason, the requirements for Research Course or CITI participation also apply to the Proxy PI.

If you have any questions about the Research Course requirement for Proxy PIs, please contact Edward E. Bartlett, PhD, IRB Administrator, at 782-7829, or via Outlook.

Recently Approved Protocols at WRAMC (cont. from page 8)

Department of Radiology	
MAJ Philip A. Dinauer, MC	02-47005: Detection of Glenoid Labral Tears and Rotator Cuff Tears: Comparison of Intravenous Contrast-Enhanced and High-Resolution Noncontrast MR Imaging of the Shoulder
MAJ John D. Statler, MC	02-47008E: A Novel Tool for Teaching Ultrasound Guided Biopsy: Trainee Satisfaction Survey
Department of Surgery	
Anesthesiology Service	
LTC Steven Cohen, MC	02-31004E: The Ability of Intravenous Ketamine to Predict Response to Dextromethorphan
Critical Care Medicine Service	
CPT William Jackson, MC	02-30000E: Characteristics of Patients Undergoing Lumbar Puncture in the Medical Intensive Care Unit
CPT William Jackson, MC	02-30001E: Vasopressin Adversely Affects Cardiac Performance in Septic Shock
General Surgery Service	
MAJ Alexander Stojadinovic, MC	02-20008: Electrical Impedence Scanning of Thyroid Nodules Prior to Thyroid Surgery: A Prospective Study
MAJ Alexander Stojadinovic, MC	02-20009: Electrical Impedence Imaginf for Early Detectin of Breast Cancer in Young Women
Otolaryngology-Head & Neck Service	
CPT Christina Gillespie, MC	02-25003E: Is the Genetic Mutation Associated with Familial Mondoni Malformation Actually a Previously Identified Dominant Mutation?
Urology Service	
COL Judd W. Moul, MC	02-2857-98e: Statistical Modeling Using Pre-Operative Prognostic Variables in Predicting Extracapsular Extension, Positive Margins and Outcome After Radical Prostatectomy for Prostatic: Retrospective Study using the CPRDR Prostate Cancer Database

(Cont on page 11)

HIPAA Privacy Role: Effect on Medical Research

Below is an excellent article written by an attorney who specializes in health law. The article summarizes the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the proposed modifications, and examines the impact on those affected. The article can be viewed at www.actmagazine.com.

Kohn AM. **HIPAA Privacy Role: Effect on Medical Research.** *Clinical Trials* 2002 Jun;11(6): 60-62.

IRB Calendar

The following Institutional Review Board (IRB) meetings will be held in the months of October, November and December 2002:

CLINICAL INVESTIGATION COMMITTEE (CIC):

01 October	05 November	03 December
15 October	19 November	10 December

HUMAN USE COMMITTEE (HUC):

08 October	12 November	17 December
22 October	26 November	

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC):
12 December

All meetings will begin at 1300, except HUC meetings which will start at 1200. All meetings will be held in the fourth floor conference room, Building 6, WRAMC.

Attention DCI Employees! Don't Forget Your BMAR!

All DCI personnel must be up to date in their BMAR training. BMAR on-line is available at:

WWW.CMECOURSES.COM/DOD

Login is the first four(4) letters of last name and the password is the last five(5) numbers of your SSN. The online BMAR takes approximately 2½ - 3 hours to complete, with a test at the end to test your knowledge of the covered material. DCI personnel are reminded to print Off their evaluation sheets after they complete the training. These sheets certify that you have completed the course

BMAR is still given didactically. The next didactic versions of BMAR will be given on 09 & 23 October, 06 & 20 November, and 04 & 11 December. All BMAR sessions are from 0730-1245 in Joel Auditorium, Bldg 2.

The following DCI personnel have birthdays in the months of October, November and December:

Eleanor Bicknell (07 October)
SSG Lance Thomas (30 October)
Wilfred Shelton (19 November)
Audrey Franklin (23 November)
Yvonne Lukes (31 December)

Recently Approved Protocols at WRAMC (cont. from page 10)

COL Judd W. Moul, MC	02-2857-98g: The Utility of Gene-Specific DNA Hypermethylation Within Diagnostic Sextant Biopsies as an Early Detection Molecular Marker of Prostate Cancer
COL Judd W. Moul, MC	02-2857-98h: Evaluation of Gene-Specific DNA Hypermethylation as a Molecular Marker to Predict Risk of Biochemical Recurrence Among Men with Clinically Localized Prostate Cancer Who Undergo Radical Prostatectomy
COL Judd W. Moul, MC	02-2871-98e: Serum Protein Patterns as Potential Diagnostic and Prognostic Biomarkers for Prostate Cancer
Deployment Health Clinical Center	
LTC Charles C. Engel, MC	02-89006: Brief Cognitive-Behavioral Treatment for Victims of Mass Violence
Telemedicine Directorate	
COL Ronald Poropatich, MC	02-87003: Benchmark Usability Study of Personal Digital Assistants (PDAs) in Clinical Practice, Participatory Design and Visioning
LTC Raul Marin, MC	02-87004: Neuromuscular Rehabilitation Via Telebiofeedback as a Portal for Home Care

Inquiring Minds is published quarterly by the Department of Clinical Investigation, WRAMC, as a service to DCI employees and the WRAMC research community.

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